Q8 Cont

in a pharmaceutically acceptable carrier, for use in the treatment of a mammal infected with hepatitis C virus.

Q9

19. (Amended) The formulation of Claim 16, wherein said α-interferon is interferon α-2b.

21. (Amended) The formulation of Claim 16, wherein said thymosin is Thymosin Fraction Five, said immune system-potentiating amount is a human immune system-potentiating amount, and said amount is from about 900 to about 1200 mg/m2 body surface area of said human.

Q10 Sub. B4

22. (Amended) The formulation of Claim 16, wherein said anti-viral effective amount of said α-interferon is from about 1 million to about 3 million units of said α-interferon.

Q11

24. (Amended) The formulation of Claim 16, wherein said thymosin is Thymosin α-1 and wherein said amount is about 1500 to about 1700 μg of Thymosin α-1.

REMARKS

Claims 1, 3-8, 10-17 and 19-24 are pending in the application. Claims 2, 9,and 18 have been cancelled. Claims 1, 3-8, 10, 11, 13, 16, 19, 21, 22 and 24 have been amended. No new matter has been added.

The Examiner has requested an update of the status of continuing information. Applicant has a new representative that is trying to determine the status of continuing information and will update same when such information is available.

Claims 2-6, 8-11, 13, 16, 18, 19, 21 and 24 have been objected to. Amendments to these claims have been made in accordance with the Examiner's suggestions.

Claims 7-9, 12-14, 16-18 and 21 have been rejected under 35 U.S.C§112, first paragraph. Applicants have amended the claims to recite that the interferon is α-interferon. This rejection is now believed overcome.

Claims 7-9, 12-14, 16-18 and 21 have been rejected under 35 USC.§102(b) or in the alternative under 35 USC§103(a) over Huang et al. Applicants respectfully traverse this rejection.

The present invention is directed to a method of treating Hepatitis C and composition for treating Hepatitis C. The present invention is improved over previous methods because it combines (1) α-interferon with (2) thymosin to treat Hepatitis C with advantageous results. The inventor found that Thymosin therapy, used in combination with interferon therapy combines the immune system potentiating effect of thymosin with the anti viral effects of interferons. Further, this permits comparable efficacy with interferon plus thymosin at lower doses than would be required with interferon alone. None of the cited references disclose this feature.

Huang et al. discloses the treatment of patients with **Hepatitis B** with a combination of interferon and thymosin. There is no disclosure of treating **Hepatitis C** with such a combination. Further, Huang et al. does not disclose the use of α-interferon in combination with thymosin or any mention of treating Hepatitis C.

Huang et al. is unhelpful because Hepatitis B virus is totally different than Hepatitis C virus. Hepatitis B is a DNA virus, whereas Hepatitis C is an RNA virus. They operate differently in a host. For Hepatitis C, the injury is mostly caused by the virus itself. For Hepatitis B, the injury is caused by the immunologic response to the virus. Therefore, no generalized assumption would have been made by one of ordinary skill in the art that a therapy that works for Hepatitis B would work for Hepatitis C or HIV or any other known viruses. Since Huang et al. does not disclose the treatment of Hepatitis C (an RNA virus) or the use of α-interferon, Huang et al. does not anticipate nor render obvious the present claims. Hence, this rejection is believed overcome.

Claims 10, 11, 15, 19, 20 and 22-24 have been rejected under 35 U.S.C. §103(a) as allegedly obvious over Huang et al, in view of Hoofnagle et al., Goldstein, et al. and Birr et al. Applicant respectfully traverses this rejection.

As stated above, the present invention is directed to a method of treating Hepatitis C and composition for treating Hepatitis C. with a combination of (1) α-interferon and (2) thymosin.

Huang et al. fails to teach the treatment of Hepatitis C (caused by an RNA virus). Huang et al. only teaches treating Hepatitis B (caused by a DNA virus). Huang et al. also fails to teach the use of α-interferon. Thus, there is no guidance to treat Hepatitis C.

Hoofnagle et al. is directed to treating Hepatitis C with α-interferon. There is no discussion of using thymosin in combination with α-interferon for treating Hepatitis C. Further, Hoofnagle et al. does not make up for the deficiencies of Huang et al. because there is no discussion or suggestion that a therapy for "B" would be beneficial for "C."

Goldstein et al. discloses that thymosin alpha 1 is immunopotentiating. There is no discussion of using thymosin of any type for treating Hepatitis or of combining thymosin with α-interferon. Hence, Goldstein, et al. also does not make up for the deficiencies of Huang et al. or add anything to Hoofnagle et al. to have led one of ordinary skill in the art to the claimed invention.

Birr et al. is directed to a method of preparing thymosin α1. Birr et al. suggests using thymosin α1 for treating cancer. There is no discussion of treating Hepatitis C and no motivation for combining thymosin with interferon to treat Hepatitis C. Further, there is no suggestion that a therapy for "B" would work for "C". Thus, Birr et al. does not make up for the deficiencies of Huang et al, Hoofnagle et al or Goldstein et al. and would not have led one of ordinary skill in the art to the present invention.

None of the cited references, whether taken alone or in combination, would have led one of ordinary skill in the art to the present invention because none of the references teach combining α-interferon with thymosin to treat Hepatitis C. To date, no one has treated Hepatitis C with a combination of α-interferon and thymosin. Hence, this rejection is believed overcome.

Versions with markings to show changes made.

IN THE SPECIFICATION

Page 6, line 7, replace "therapya" with ---therapy---.

Page 7, line 16, replace "therefore" with ---Therefore---.

Page 13, line 7, replace "subsutaneous" with ---subcutaneious---;

Line 23, replace "period" with ---prior---.

IN THE CLAIMS

Please amend the following claims:

1. (Amended) A method of treating a mammal infected with hepatitis C virus, comprising administering to said mammal an anti-viral effective amount of at least one α-interferon, concurrently or consequentially with administering [said] a thymosin or thymosin fragment.

Please cancel claim 2.

3. (Amended) [A] The method of claim [2] 1, wherein said α-interferon is interferon α-2b.

4. (Amended) [A] The method of Claim 1, wherein the step of administering said interferon comprises administering interferon produced by recombinant DNA technology.

5. (Amended) [A] The method of Claim 1, wherein said mammal is a human [, said interferon is an α-interferon,] and the amount of said interferon administered ranges between about one million and about three million units of said interferon per administration.

6. (Amended) [A] The method of Claim 1, wherein said mammal is human, said thymosin is thymosin α-1, and said dose is about 1500 to about 1700 μg of said thymosin α-1.

7. (Amended) A composition comprising a pharmaceutical dosage unit of a pharmaceutically acceptable carrier containing an immune system-potentiating amount of at least one member selected from the group consisting of thymosin and immune system-

potentiating fragments of thymosin in combination with an anti-viral effective amount of at least one α-interferon, said pharmaceutical dosage unit being capable of promoting *in vivo* [in vivo] inactivation of hepatitis C virus when administered to mammals infected with said virus.

8. (Amended) [A] The composition of Claim 7, wherein said thymosin is selected from the group consisting of Thymosin Fraction five and Thymosin α-1.

Please cancel claim 9.

10. (Amended) The method of claim [9] 7, wherein said α-interferon is interferon α-2b.

11. (Amended) [A] The method of claim 10, wherein said interferon is recombinant interferon.

13. (Amended) The composition of Claim 7, wherein said [interferon is an] α-interferon [αinterferon and said] is present in an amount [is] between about 1 million and about 3 million units of said interferon.

16. (Amended) An anti-hepatitis C formulation comprising an immune [sytem] system-potentiating amount of at least one thymosin or an immune system-potentiating thymosin fragment in combination with an anti-viral effective amount of at least one α-interferon in a pharmaceutically acceptable carrier, for use in the treatment of a mammal infected with hepatitis C virus.

Please cancel claim 18.

19. (Amended) The formulation of Claim [18] 16, wherein said α-interferon is interferon α-2[B]b.

21. (Amended) The formulation [forumlation]of Claim 16, wherein said thymosin is Thymosin Fraction Five, said immune system-potentiating amount is a human immune system-potentiating amount, and said amount is from about 900 to about 1200 mg/m2 body surface area of said human.

22. (Amended) The formulation of Claim 16, wherein said [interferon is α-interferon and wherein said] anti-viral effective amount of said α-interferon is from about 1 million to about 3 million units of said α-interferon.

24. (Amended) The formulation of Claim 16, wherein said thymosin is [Thuymosin] Thymosin α-1 and wherein said amount is about 1500 to about 1700 μg of Thymosin α-1.

The application is now believed to be in condition for allowance. Reconsideration and allowance are respectfully requested.

Respectfully submitted,

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